4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0194]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Cover Sheet; Form FDA 3792

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title "Biosimilars User Fee Cover Sheet; Form FDA 3792". Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biosimilars User Fee Cover Sheet; Form FDA 3792--(OMB Control Number 0910-New)

The March 23, 2010 Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the Public Health Service Act (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act, added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product. The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379g) to include 351(k) applications in the definition of "human drug application" for the purposes of the prescription drug user fee provisions. The authority conferred by the FD&C Act's prescription drug user fee provisions expires in September 2012. The BPCI Act directs FDA to develop recommendations for a biosimilar biological product user fee program for FYs 2013 through 2017. FDA's recommendations for a biosimilar biological product user fee program were submitted to Congress on January 13, 2012. If enacted into law, FDA's proposed biosimilar biological product user fee program would require FDA to assess and collect user fees for certain meetings concerning biosimilar biological product development (BPD meetings),

investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biological product applications and supplements. Proposed Form FDA 3792, the Biosimilars User Fee Cover Sheet, requests the minimum necessary information to determine the amount of the fee required, and to account for and track user fees. The form would provide a cross-reference of the fees submitted for a submission with the actual submission by using a unique number tracking system. The information collected would be used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of biosimilar biological product INDs, applications, and supplements, and to account for and track user fees associated with BPD meetings.

In the Federal Register of March 13, 2012 (77 FR 14809), FDA published a 60-day notice requesting public comment on the proposed collection of information, Form FDA 3792, the Biosimilar User Fee Cover Sheet. FDA received the following comments:

(Comment 1) Suggests FDA use the term "Biosimilar Biological Product Licensing Application (BBLA)" or "Interchangeable Biosimilar Biological Product Application (IBLA)" for a biosimilar application instead of Biologics License Application (BLA) to avoid confusion and provide greater clarity.

(Response) FDA notes the Biosimilar User Fee Cover Sheet serves a billing and collections purpose, and does not indicate FDA's position on reference terms. However, to maintain consistency throughout the document and avoid any confusion, FDA refers to a biologics license application submitted under section 351(k) of the Public Health Service Act as a "351(k) application". Under FDA's proposed biosimilar biological product user fee program, user fees would be assessed only for those 351(k) applications that fall within the scope of the

defined term "biosimilar biological product application." Accordingly, FDA has made changes to the Biosimilar User Fee Cover Sheet to clarify that Form 3792 need not be submitted for certain specified types of 351(k) applications. Additionally, to address the need for greater clarity, FDA has added definitions of several other key terms to the Biosimilar User Fee Cover Sheet.

(Comment 2) Requests FDA to ask for all available product names, including the product's code name in addition to trade and proper names, because the Biosimilar User Fee Cover Sheet should be consistent with Form FDA 1571. Further, requests FDA to amend the "Product Name" information field to "Product Name(s)."

(Response) We agree that the Biosimilar User Fee Cover sheet should be consistent with Form 1571, where applicable. Accordingly, FDA amended the instructions to request proper name, trade or proprietary name, and code name, as applicable, and amended the "Product Name" information field to "Product Name(s)".

(Comment 3) Requests FDA to remove the question about whether the application requires clinical data, other than comparative bioavailability studies, for approval because this information does not affect the fee amount.

(Response) FDA notes this question applies only to fees for biosimilar biological product applications, and not to fees for biosimilar biological products in development. Under FDA's proposed biosimilar biological product user fee program, the fee amount for a biosimilar biological product application depends on whether clinical data with respect to safety or effectiveness are required. Specifically:

- A full fee is assessed for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval;

- a half fee is assessed for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval;

- a half fee is assessed for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval; and

- no fee is assessed for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval.

Therefore, FDA has retained the question on the Biosimilar User Fee Cover Sheet concerning whether clinical data are required because it requests information necessary to determine the fee amount for a biosimilar biological product application or supplement.

(Comment 4) Requests FDA to decline to require a patent certification as part of a 351(k) application.

(Response) FDA notes this comment is outside the scope of the proposed collection of information, Form FDA 3792, the Biosimilar User Fee Cover Sheet.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
FDA 3792	9	1	9	0.5 (30 minutes)	4.5

[1]There are no capital costs or operating maintenance costs associated with this collection of information.

Respondents to this proposed collection of information would be manufacturers of biosimilar biological product candidates. Based on FDA's database system, there are an estimated 18 manufacturers that fall into this category. However, not all manufacturers will have submissions in a given year and some may have multiple submissions. FDA estimates 9 annual responses that include the following: 6 INDs or BPD meetings, 2 applications, and 1 supplement. The estimated hours per response are based on FDA's past experience with other submissions, which average 30 minutes.

Dated: June 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-14740 Filed 06/15/2012 at 8:45 am; Publication Date: 06/18/2012]